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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,436	CASTILLO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-18,22 and 24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21,23 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group III, claims 19, 20, 21, 23, and 31-38 in the reply filed on 26 April 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's election of the species "Alzheimer's disease" and "Fraction H" in the reply filed on 26 April 2006 is also acknowledged.

Claim Objections

Claims 19, 20, 21, 23, 31, and 33-38 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Although the cited claims depend from non-elected claims, please note that - as drafted, claims 19, 20, 21, 23, 31, and 33-38 are improper multiple dependent claims - including because a number of the non-elected claims from which these claims depend are also multiple dependent claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 20, 21, 23, and 31-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 20, and 23 are rendered vague and indefinite by the respective phrases "A composition further referred to herein as PTI-777", "A composition further referred to herein as a PTI-777 fraction", and " A composition further referred to herein as compound H" because it is very unclear as to what these phrases are attempting to define - e.g., a composition comprising PTI-777 (and/or a subset thereof), a PTI-777 fraction, or compound H; a composition consisting essentially of PTI-777 (and/or a subset thereof), a PTI-777 fraction , or compound H; a composition consisting of PTI-777 (and/or a subset thereof); a PTI-777 fraction, or compound H; or are these phrases attempting to define that the composition is simply PTI-777, a PTI-777 fraction, or compound H, *per se*? Further, these phrases are unclear as to the source of the recited components. It is suggested, at a minimum, that these phrases be amended to recite --A composition comprising PTI-777 isolated from *Uncaria tomentosa*--, --A composition comprising a PTI-777 fraction isolated from *Uncaria tomentosa* --, and --A composition comprising compound H isolated from *Uncaria tomentosa*--, respectively.

Claims 31 (and dependent claims therefrom) is rendered exceedingly vague and indefinite by the phrase "pharmaceutical agent comprising a therapeutically effective amount of a material made according to the process of claims 1, 8, 10-13, 18, and 22" (lines 1-2) because it is totally unclear as to what material from the methods of claims 1, 8, 10-13, 18, and 22 is being defined thereby – e.g., with respect to the preparatory process of claim 18: is the material of claim 31 attempting to define the dried, solid material obtained in step (f) and used in step (g); is it the set of active fractions obtained in step (k), is it one or more of the fractions obtained in step (q) or something else? Please note that other than the step (f)-(g) solid material, the term "material" in claim 31 lacks antecedent basis with claim 18 (as well as with the other

preparatory method claims). It would appear that Applicants actually intend the pharmaceutical product to comprise a therapeutically effective amount of one or more of the final separated, collected fractions obtained from one of the various preparatory method claims. As such, this should be clearly defined in step 31 (especially since these final separated, collected fractions are considered essential elements of the pharmaceutical product of claim 31, based upon the overall teachings of the instant specification – see, e.g.., MPEP 2172.01). In addition, "pharmaceutical agent comprising" is unclear and confusing because this would imply a singular agent, whereas it would seem more appropriate and clear to define the claimed product as a pharmaceutical composition comprising a therapeutically effective amount of one or more of the fractions obtained therefrom.

All other cited (elected) claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 19, 20, 21, 23, and 31-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19, 20, 21, 23, and 31-38 of copending Application No. 10/624,435. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented (please note that all other non-elected claims would also be rejected under provisional statutory double patenting, as all the claims in both Applications are identical).

With respect to the prior art of record, a composition comprising the elected species "compound H" (isolated from *Uncaria tomentosa*) was found free of the art. Accordingly, the examiner searched and examined other compound/fraction species (isolated from *Uncaria tomentosa* via the instantly claimed/disclosed process steps) from among those claimed/disclosed - i.e., PTI-777, and fractions F, G, I, J, K_1, K_2, L, M, N, O. All of these other species were also found free of the art with the exception of fraction F (which, as readily admitted by Applicants, reads upon chlorogenic acid) and fraction J (which, as readily admitted by Applicants, reads upon epicatechin). Thus, the art rejections set forth below concern compositions comprising fraction F (chlorogenic acid) and fraction J (epicatechin). To hasten prosecution, it is strongly suggested that Applicants amend the claims so as to omit fractions F and J from the claim language, as well as cancel claim 32, to overcome the art rejections below.

In addition, to hasten prosecution, with respect to the non-elected claims - in anticipation of rejoining the instant method claims with potential subsequent allowable product claims, it is suggested that a complete preparatory method be recited within the independent method of making claims that actually results in the isolation of the various recited fractions (or of PTI-777) - e.g., via incorporating the subject matter of claims 10 and 11 into claim 1, incorporating the subject matter of claims 10 and 12 into claim 1, and/or incorporating the subject matter of claims 10 and 13 into claim 1 (so as to properly define a complete process resulting in the isolation of such compounds/fractions). Further, any recitation drawn to "prevention" within the claim language should be omitted from all method of use claims so as to obviate any enablement issues. All improper multiple dependent claims should also be appropriately amended. Please further note that rejoinder of preparatory method claims would require a proper Terminal Disclaimer to overcome a potential obviousness-type double patenting rejection over the claims in U.S. Patent No. 6,929,808 (which is the parent of the instant "Divisional" Application).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa Co (JP 04145048 - DWPI Abstract) or by Hasegawa Co (JP 04145049 - DWPI Abstract), or by Vitasyn GMBH (DE 19627344 – DWPI Abstract), to name a few.

A pharmaceutical agent and/or pharmaceutical composition comprising fraction F (chlorogenic acid) or fraction J (epicatechin) is claimed.

Each of the cited Hasegawa references teaches compositions for use within pharmaceuticals which comprising chlorogenic acid (which, as readily admitted by Applicants, reads upon fraction F - see, e.g., Example 13 on pages 45-47 of the instant specification) as the active ingredient therein (see DWPI Abstracts).

Vitasyn GMBH teaches a composition comprising a therapeutically effective amount of epicatechin therein (within the approximate dosage levels instantly claimed) – see DWPI abstract. As readily admitted by Applicants, "fraction J" (one of the preferred separated, collected bioactive fractions obtained in final step q of claim 18) was identified as epicatechin (see, e.g., pages 48-49, Example 16). Since fraction J represents epicatechin, the pharmaceutical product taught by Vitasyn GMBH comprising therapeutically effective amounts of epicatechin therein reads upon the instant product claims.

Accordingly, each of the cited references is deemed to anticipate the instant claims above.

Claims 20 and 31-38 are rejected under 35 U.S.C. 102(b) as being anticipated by the admitted state of the art, with evidence provided by the Sigma Chemical Co. catalog (1994 ed) and the Aldrich Chemical Co. catalog (1990-1991 ed).

As readily admitted by Applicants, commercial chlorogenic acid such as sold by Sigma Chemical Co. or by Aldrich Chemical Co. effectively provide the instantly claimed/disclosed functional effect (see, e.g., page 47, lines 20-23, of the instant specification).

Accordingly, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa Co (JP 04145048 - DWPI Abstract) or by Hasegawa Co (JP 04145049 - DWPI Abstract) and the Sigma Chemical Co. catalog (1994 ed) or the Aldrich Chemical Co. catalog (1990-1991 ed).

Each of the JP references teaches compositions for use within pharmaceuticals comprising chlorogenic acid (which, as readily admitted by Applicants, reads upon fraction F - see, e.g., Example 13 on pages 45-47 of the instant specification) as the active ingredient therein (see DWPI Abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare pharmaceutical compositions comprising chlorogenic acid as an active ingredient therein based upon the beneficial teachings provided by each of the JP reference; as well as to substitute and/or incorporate a readily available commercial source of purified chlorogenic acid such as that manufactured and sold from Sigma Chem. Co and/or Aldrich Chemical Co. within such a pharmaceutical composition given the beneficial teachings provided by the Hasegawa references with respect to the advantageous use of chlorogenic acid as an active ingredient within pharmaceuticals.

Thus, the invention as a whole is clearly *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 20 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitasyn GMBH (DE 19627344 – DWPI Abstract), to name one of numerous art-recognized prior art epicatechin-containing pharmaceutical compositions.

The teachings of Vitasyn GMBH are relied upon for the reasons discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare pharmaceutical compositions comprising epicatechin as an active ingredient therein based upon the beneficial teachings provided by Vitasyn with respect to such pharmaceutical preparations.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

With respect to the art rejections above, it is noted that the references do not teach that the reference compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference compositions (see, e.g., MPEP 2112). In addition, please note that the instantly claimed functional effect/activity would be inherent to such chlorogenic acid and/or epicatechin compositions.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655